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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,858	04/08/2005	Giorgio Bertolini	2002IT302	4422
38263	7590	10/25/2007		
PROPAT, L.L.C. 425-C SOUTH SHARON AMITY ROAD CHARLOTTE, NC 28211-2841			EXAMINER CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			10/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,858	BERTOLINI ET AL.	
	Examiner	Art Unit	
	Yong Chu	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 12, 13, 15-17 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 6, 10, 11, 14, 18, 19, and 23-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/20/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26 are currently pending in the instant application.

Information Disclosure Statement

Applicant's Information Disclosure Statement, filed 05/20/2005 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

Priority

This application is a 371 of PCT/IB03/04498 filed 10/13/2003, claims the benefit of Italy Patent Application MI2002A 002172, filed 10/14/2002.

Status of the Claims

Claims 1-26 will be examined on the merits.

Specification

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

Claim Objections

Claims 6, 10, 11, 14, 18-19, and 23-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 27 is objected to because of the following informalities: There is a typo at claim 27, because there are two claims 26. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 recites the limitation "the hydrogenation catalyst is palladium supported on an inert support" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

Claims 21 and 22 recite the limitation "an inert support" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

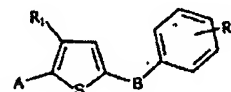
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-5, 7-9, 12, 13, and 15-17 are rejected under 35 U.S.C. 103 (a) as unpatentable over Dollings et al., *U.S. Patent No. 6,103,708* (the '708 patent) in view of the teaching of Campanati et al. *Chemical Industries*, 1998, 75 (catalysis of organic reactions), pp.307-318.

Applicant's instantly elected invention in claim 1-5, 7-9, 12, 13, and 15-17 relates

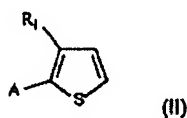
to a process for preparing pharmaceutical intermediate of formula (I)



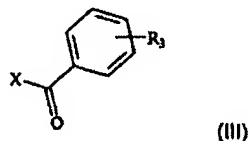
wherein

B is a -CHOH or CH₂ group, comprising the steps of

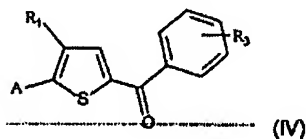
(a) the reaction of a compound of formula



with a compound of formula



to give a compound of formula



in which

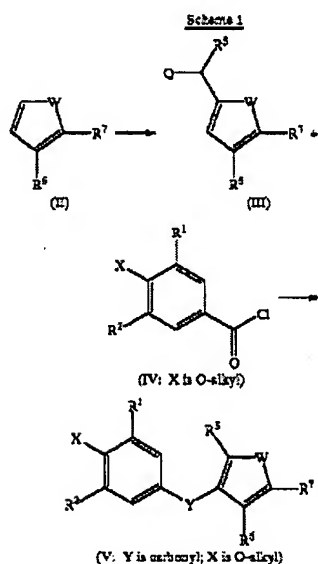
A, R₁, R₂ and R₃ have the meanings given above; and

(b) the reduction of the compound of formula IV thus obtained to give the compound of formula I.

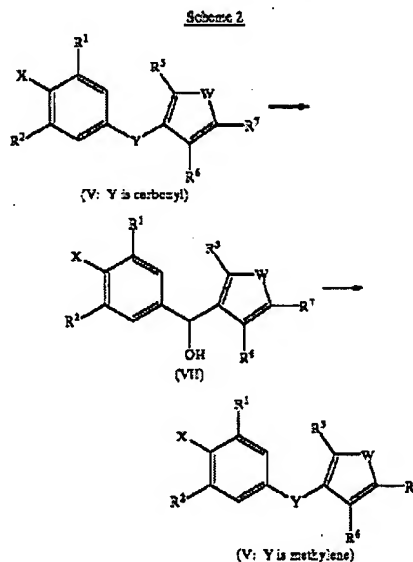
Determination of the scope and content of the prior art (MPEP §2141.01)

The '708 patent discloses a process for preparing phenyl substituted thiophenes

of formulae (VII) and (V) by reacting substituted thiophene with substituted benzoyl chloride in the presence of N-butyl lithium, followed by the reduction of the ketone with lithium aluminum hydride in an aprotic solvent, and further reduction of the resulting alcohol (VII) to compound (V) with triethylsilane in the presence of boron trifluoride diethyl etherate, as illustrated in Scheme 1



, and Scheme 2



Campanati et al. teach a process of making substituted phenyl(thiophen-2-yl)methanone by acylation of thiophene with a substituted benzoyl chloride in the presence of Lewis acid $AlCl_3$.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the process in the '708 patent and the instantly claimed

process is that the reagents used for acylation in Scheme 1 is different, strong base of n-butyl lithium is used in the prior art, and Lewis acid (i.e. AlCl_3) catalyzed acylation (also called Friedel-Crafts acylation reaction) is claimed for the instant application.

Finding of prima facie obviousness - rationale and motivation (MPEP § 2142-2413)

It would have been obvious the process for one having ordinary skill in the art at the time the invention to use the process in the '708 patent with teaching and suggestion from Campanati et al. The motivation for combining such two references is for making the same type products. Use Lewis acid (i.e. AlCl_3) catalyzed acylation of aromatic ring is called Friedel-Crafts acylation reaction, a well known to one skilled in the chemistry art. The general statement of crystallization method of purification of the compounds in claims 12 and 15 without specifying the solvent is obvious to one skilled in the chemistry art, because it is taught in chemistry textbook that an aromatic compound can be purified with crystallization method as a common practice.

Even though the starting material and the final products to make may be different, such variation does not change the required process, and can be obvious to one skilled in the art to apply the prior art teaching to the instantly claimed process. The chemical process that is occurring is an expected reaction. The use of a novel and unobvious starting material, or a novel and unobvious final product, does not render an obvious, predictable process patentable. In re Durden, 763 F. 2d 1405, 226 U.S.P.Q 359 (Fed. Cir. 1985).

Also as stated in the related case law, the selection of reaction conditions is more optimization by more modification of routine experimentation and within one skilled in

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the art. Changes in temperature, concentration, or both are not patentable modification in the absence of unexpected results, which are different in kind, and not degree. In re Aller, 105 USPQ 233. Discovery of an optimum value of a result effective variable is not patentable if such discovery is within one skilled in the art. A prima facie case of obviousness may be rebutted in optimizing a variable only when results are unexpectedly good. In re Boesch, 205 USPQ 215.

Conclusion

- Claims 6, 10, 11, 14, 18-19, and 23-27 are objected.
- Claims 1-5, 7-9, 12, 13, 15-17, 20-22 are rejected

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

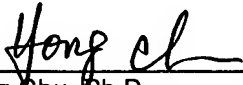
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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